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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,016	05/15/2001	Jane C. Hirsh	21720	4877

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	18

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/858,016	HIRSH ET AL	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *14* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Request for Continued Examination, Extension of Time, and Amendment D received on June 16, 2003 is acknowledged. Claims 33-57 are included in the prosecution of this application. Claims 1-3, 5-19, 22-29, and 32 stand cancelled.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection based on Amendment D.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33, 35, 38-39, 41, 43, 44, 46, and 48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 5-6, 8, 10, and 16 of copending Application No. 10/015930. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications contain similar subject matter.

Instant application claims a composition and a process of preparation with an intraoral portion for sublingual or buccal administration, specific drugs, drug amount, and a second oral portion to be released in the GI tract. Claim 35 recites the composition in a tablet or capsule form. Claims 38-39 claims a film coating. Claim 41 claims an effervescent agent in the outer coating. Claim 43 recites a sustained release formulation. Claims 44 and 46 claim a release rate of 0.5-24 hours. Claim 48 claims the outer layer dissolves within 10 minutes.

Co-pending application claims a composition and a process of preparation with an intraoral portion for sublingual or buccal administration and a second oral portion to be released in the GI tract. Claim 2 recites the composition in a tablet or compressed tablet form. Claim 6 claims a film coating. Claim 5 claims an effervescent agent in the outer coating. Claim 8 and 10 recite a sustained release formulation and a release rate of 0.5-24 hours. Claim 16 claims the outer layer dissolves within 10 minutes.

The two applications are related as genus-species. Co-pending recites a broader composition (genus) and the instant application recites a species of drugs. Instant application claims a broad sustained release formulation whereas the co-pending recites a specific sustained release composition. Instant application claims a specific outer film coating in dependent claims whereas co-pending claims a generic outer film coating.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 47 recites a second chewable portion in the oral component, which is indefinite since the invention as set forth by specification and arguments pertaining to intended use defines the oral component as the area which is swallowed. Therefore, it is unclear how the oral portion contains a chewable medication if it is swallowed.

Claim 51 recites a broad number of drug categories; however claim 51 depends on claim 33, which recites specific drugs. Therefore, it is unclear what claim 51 is intended to claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33-43, 45, 47, 49-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al (5,053,032).

Barclay et al disclose an osmotic device for delivering a beneficial agent. Barclay's tablet houses two regions, one for buccal administration of a drug and a second region for delivering a drug to the GI tract (Note abstract, col. 8, lines 28-51). Further, the tablet contains a signaling in the form of a flavoring agent or coloring agent that alerts the patient that the buccal administration dosage has been delivered and the remainder may be swallowed (col. 3, lines 57-68, col. 5, lines 25-55). The reference discloses several drugs including instant drug prochlorperazine, nitroglycerine, etc. that are suitable for the delivery device on column 10, line 50 to column 11, lines 35). The instant amount of the drug is taught on column 12, lines 23. Barclay discloses the process of making the device and compression of the layers (example 1). Osmagents such as sodium carbonate are taught in the osmotic device. See column 12 lines 27-45. In one example an ibuprofen and HPMC layer overcoat a device containing ibuprofen, excipients, and a signaling system. See example 3.

Barclay does not exemplify the instant drugs.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to utilize the instant drugs since Barclay teaches various drugs including instant drugs that are suitable for use in the invention. Therefore, one would be motivated to use the drug of choice depending on the symptom to be treated.

Claims 33-43, 45, 47-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin (5,702,723) in view of WO 98/43235.

Griffin teaches a multi-stage oil having an outer layer comprising an active substance that will dissolve, an inert layer, and a core with a substance that works within the body such as the gastrointestinal tract or systemically. See column 3, lines 1-12. The coating is quick dissolving and contains a flavor or sweetener. The outer coating can include calcium carbonate, etc. See column 4, line 3. The coating is made of HPMC and plasticizers. The inert layer acts to control the rate of release if desired. See column 4, lines 5-23. Griffin teaches many possible drug combinations for the buccal administration and the GI administration such as analgesic, antibiotics, etc.

Griffin does not teach the instant drug and dosage.

Lewis et al teach an analgesic composition that may be in a sublingual form or parenteral. The analgesic, buprenorphine, is included in the therapeutic amount of 0.1 mg to 0.4 mg sublingually for the treatment of pain. See column 2, lines 61-66.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Griffin and Lewis et al and incorporate the instant drug and dosage amount. One would be motivated to look at Lewis since Lewis teaches the use of buprenorphine to treat pain in the instant amount sublingually. Further, one would expect similar results and success by using instant drug since Griffin discloses the use of analgesics and further states that the use of other drugs is apparent to those skilled in the art.

Claims 44 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentabl over Griffin (5,702,723) in view of Jordan et al (4,814, 181).

As set forth above, Griffin teaches a multi-stage oil having an outer layer comprising an active substance that will dissolve, an inert layer, and a core with a substance that works within the body such as the gastrointestinal tract or systemically. See column 3, lines 1-12. The coating is quick dissolving and contains a flavor or sweetener. The outer coating can include calcium carbonate, etc. See column 4, line 3. The coating is made of HPMC. The inert layer acts to control the rate of release if desired. The thickness and composition of the layer determines the release of the active. Polymers such as HPMC and EVAC cellulose or other suitable materials in the art may be used to obtain these results. See column 4, lines 5-23. Griffin teaches many possible drug combinations for the buccal administration and the GI administration such as analgesic, antibiotics, etc.

Griffin does not specifically teach the time period of the sustained release.

Jordan et al teach a dosage form containing a fast agent delivery and a slow agent delivery. Jordan teaches the method of making fast releasing layers and slow releasing layers by manipulating the components in the composition to obtain the desired delivery rate col.4, line 53 to col. 7, line 20). The fast release lamina is taught to deliver in the first hours of operation and the slow releasing lamina is taught to release between 1.5 to 14 hours (col. 4, line 36 to col. 5, lines 37). Jordan teaches the instant polymers such as PEG and HPMC to manipulate the release rate. Further, Jordan

teaches the inclusion of effervescent agents in the fast lamina to increase the disintegration time.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Griffin and Jordan et al. One would be motivated to do so since Jordan et al teaches the manipulation of components in a dosage form to vary the release rates. Further motivation to do so with a reasonable expectation of success is that Griffin teaches that the layer's composition may be manipulated to the desired release rate. Therefore, one would be motivated to manipulate the prior art's composition to yield the desired release rate.

Claims 33-39 and 42-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 800,973 in view of Leslie et al (4,322,433).

GB teaches a multi-layered tablet wherein the outer coating contains a medicament that readily dissolves in the mouth, a signal layer containing a distinctive flavor, an enteric layer, and an oral medicament layer to be swallowed. See figures. GB discloses that the enteric layer may be manipulated with a certain thickness to release the medicament in a given area or time, which is known in the art. See page 2. Drugs that are suitable are nitroglycerine in a therapeutically effective amount. See example 2.

GB does not specify the dosage.

Leslie et al teach percutaneous administration of nitroglycerine. Leslie teaches 0.15 mg/tablet for oral administration and 0.60 mg/tablet for sublingual for the treatment of angina. See column 1, lines 49-51.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of GB and Leslie et al and utilize the instant amount of nitroglycerine. One would be motivated to do so since Leslie teaches that 0.60mg is utilized in a sublingual tablet to treat angina. Therefore, one would be motivated to utilize the instant amount of nitroglycerine to treat angina.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG
August 27, 2003

MICHAEL G. HARTLEY
PRIMARY EXAMINER